



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 25, 2020

Jennifer Reeder
Director, Regulatory Affairs
Steris Corporation
P.O. Box 147
St. Louis, MO 63166

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Vesphene II se
EPA Registration Number: 1043-87
Application Date: 3/16/2020
Decision Number: 560818

Dear Ms. Reeder:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HSAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is enveloped viruses.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Adenovirus Type 2 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



John Hebert, Chief
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

VESPHENE® IIse
ONE-STEP GERMICIDAL DETERGENT
EPA REG. NO. 1043-87 EPA Est. No. 1043-MO-2

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

Germicide □ Fungicide □ Virucide* □ Tuberculocide Deodorizer □ Cleaner □ Detergent

Active Ingredients:

o-phenylphenol..... 9.09%
p-tertiary amylphenol.....7.66%

Inert Ingredients..... 83.25%

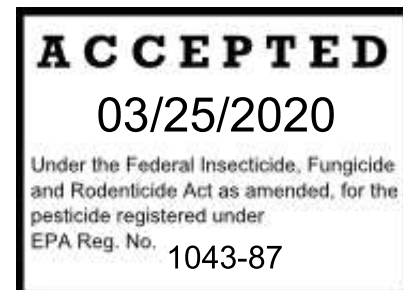
Total100.00%

FIRST AID	
If inhaled	<ul style="list-style-type: none"> •Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. •Call a poison control center or doctor for further treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> •Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> •Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. •Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> •Call poison control center or doctor immediately for treatment advice. •Have person sip a glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

KEEP OUT OF REACH OF CHILDREN
DANGER

See side panel for additional precautionary statements.

NET CONTENTS:
STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133 U.S.A.



STERILE UNLESS PACKAGING IS COMPROMISED

03/18/2020

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS: Corrosive; Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed.

(For 5 gal. or larger containers) ENVIRONMENTAL HAZARD STATEMENT: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA

This product represents a germicidal detergent system that is both research-developed and state of the art technology. It is effective in hard water and in the presence of serum. It has been formulated as a concentrate to clean, disinfect and deodorize simultaneously. Use this product for easy cleaning and disinfecting of all washable hard, non-porous environmental surfaces such as floors, walls, woodwork, bathroom fixtures, equipment and furniture. It may be used for cleaning and disinfecting chrome, stainless steel, other metal surfaces, porcelain, glass, tile, washable painted or varnished surfaces, as well as resilient vinyl, asphalt, linoleum, terrazzo or other combination type floors. This product is not for use in the neonatal (newborn) units in hospitals, specifically isolates and other infant contact surfaces.

This germicidal detergent is intended for use in institutions such as hospitals and nursing homes, industrial plants, medical and dental offices, pharmaceutical plants, veterinary clinics and other indoor areas where disinfection, cleaning and deodorizing are a necessity.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semicritical medical devices prior to sterilization or high level disinfection.

GERMICIDAL: Passes A.O.A.C. Germicidal Use-Dilution Method (*S. aureus*, *S. choleraesuis*, *Ps. aeruginosa*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

BROAD SPECTRUM DATA: In addition, the following organisms pass the A.O.A.C. Use-Dilution Test in 400 ppm A.O.A.C. hard water at a dilution of 1:128 in the presence of 5% organic soil (serum), 10 minutes at 20°C.

Acinetobacter calcoaceticus, ATCC 19606
Candida albicans, Clinical Isolate
Candida parapsilosis, Clinical Isolate
Citrobacter freundii, ATCC 8090
Enterobacter aerogenes, ATCC 13048
Enterobacter cloacae, ATCC 23355
Escherichia coli, ATCC 25922
Klebsiella pneumoniae, ATCC 13883
Staphylococcus aureus, (MRSA),
Multiply (Methicillin)-Resistant
Clinical Isolate

Proteus vulgaris, ATCC 13315
Pseudomonas aeruginosa, ATCC 27853
Pseudomonas cepacia, ATCC 25416
Salmonella typhi, ATCC 6539
Salmonella typhimurium, ATCC 14028
Serratia marcescens, ATCC 8100
Shigella flexneri, ATCC 12022
Shigella sonnei, ATCC 25931
Staphylococcus aureus, ATCC 25923
Staphylococcus epidermidis, ATCC 12228
Streptococcus faecalis, ATCC 19433

Proteus mirabilis, Clinical Isolate

Streptococcus pyogenes, ATCC 19615

Vesphene II se is effective in 3 minutes at 20°C against Pseudomonas aeruginosa ATCC 13388, according to the A.O.A.C. Use Dilution Test when diluted with 400 ppm hard water to make a 1:64 (2 ounces per gallon) solution, in the presence of 5% added organic soil (serum).

FUNGICIDAL: Passes A.O.A.C. Fungicidal Test (T. mentagrophytes) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: Passes A.O.A.C. Tuberculocidal Test (Mycobacterium tuberculosis, var. bovis) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

***VIRUCIDAL:** Passes Virucidal Assay (EPA Proposed Method) [Influenza A₂ (Japan), Herpes Simplex Type 2, Vaccinia Virus, and Adenovirus Type 2, Avian Infectious Bronchitis, Avian Laryngotracheitis, Avian Newcastle Disease, and Porcine Pseudorabies], when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution in the presence of 5% organic soil (serum) in 10 minutes at 20°C.

†When tested by an EPA-approved Dilution Method, the HIV-1(AIDS) virus, with added 10% organic soil (serum), was completely inactivated by a 1:128 (1 ounce per 1 gallon) solution in 400 ppm A.O.A.C. hard water in 60 seconds at 20-25°C. Although efficacy at 1 minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed.

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

or

Kills Pandemic 2009 H1N1 influenza A virus formerly called swine flu.

ODOR CONTROL: It eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant fragrance.

.DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES: Add 1 fl. oz. (30 cc) to each measured gallon of water used (*or Add 2 fl. oz. (59.1 mL) to two gallons of pre-measured water used*). Always add this product to pre-measured water. Thoroughly mix solution until uniform. Apply solution with a cloth, sponge, mop or brush using normal cleaning methods. Allow treated surfaces to soak for 10 minutes. Then remove excess solution with a wrung-out applicator. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution daily or when it becomes dirty and replace with a fresh solution. A properly prepared solution of Vesphene IIse intended for use as a hard surface disinfectant has a shelf life of 14 days (use life) when stored in a closed container such as a spray bottle. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix. Use only as directed.

(For measured dose bottle) CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES: To make a one gallon (1:128) solution, loosen cap from dispensing chamber. Gently squeeze bottle to fill measuring chamber to the 1 fluid ounce line (30 cc.). Remove cap from the dispensing chamber. Pour measured product (concentrate) from the chamber into one gallon premeasured cold water. Apply solution with a cloth, sponge, mop, brush or from spray bottle using normal cleaning methods. Treated surfaces should remain wet for 10 minutes. Then remove excess solution with a wrung-out applicator. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution daily or when it becomes dirty and replace with a fresh solution. A properly prepared solution of Vesphene IIse intended for use as a hard surface disinfectant has a shelf life of 14 days (use life) when stored in a closed container

such as a spray bottle. This is a complete product. Do not add other chemicals. If frozen, thaw and remix. Use only as directed.

SOLUTION TABLE FOR CONCENTRATE

Water	1 Gallon	**2 gallons	5 Gallons
Concentrate	1 fl. oz.	**2 fl. oz.	5 fl. oz.

(** For 2 oz. Foil Packet)

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of a 1:128 use-solution (1 ounce per 1 gallon). Prepare and apply solution as directed in paragraph above.

Contact Time: While the HIV-1 virus is inactivated in 1 minute, use a 10-minute contact time for disinfection of all organisms on this label.

Infectious Materials Disposal: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

For Interim Instrument Decontamination prior to Terminal Cleaning and Sterilization of Surgical Instruments and Apparatus: The removal of heavy soils and the cleaning of all surfaces prior to application of this product is required. All instruments and devices must be thoroughly cleaned to remove excess organic debris, rinsed and then rough dried before immersion. Clean and rinse the lumens of hollow instruments before filling with solution. After cleaning, immerse articles and wet all surfaces thoroughly in a 1:128 solution for 10 minutes. Rinse and dry. Not recommended for prolonged storage of instruments. Avoid splashing and cover, where possible, when transporting soiled instruments. Prepare a new solution daily or when solution turns cloudy or dirty for decontaminating pre-cleaned items.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL: This germicide, its solutions or rinsings from empty containers, should be disposed of in a toilet or service sink served by a sanitary sewer, or in a landfill approved for pesticides.

CONTAINER DISPOSAL:

(For Packet:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

(For ≤5 gal.): Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(For > 5 gal.): Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip

container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

GENERAL: Consult Federal, State, or Local disposal authorities for approved alternative procedures such as limited open burning.

This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Adenovirus Type 2

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.